

Remarks

Introduction

Claims 25-31 were pending. By way of this response, claim 25 has been amended and claims 29 and 30 have been cancelled without prejudice. Claim 25 has been amended to include the subject matter of claim 29. Support for the amendments to the claims can be found in the specification as filed, and care has been taken to avoid adding new matter. Accordingly, claims 25-28 and 31 remain pending.

Rejection Under 35 U.S.C. § 102

Claims 25-29 and 31 remain rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Dolly et al. (U.S. Patent No. 6,203,794). Claims 25-26, and 28 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by WO 94/21684.

Applicant traverses each of the rejections as it pertains to the present claims.

With regard to the rejections over WO 94/21684, claim 25 has been amended to include the subject matter of claim 29. Claim 29 was not anticipated by WO 94/21684. Therefore, applicant submits that WO 94/21684 does not anticipate present claim 25 or the claims dependent therefrom.

With regard to Dolly, applicant traverses the rejection as it relates to the present claims.

As indicated in the Office Action, the Examiner appears to be of the opinion that Dolly discloses a recombinant botulinum toxin protein that includes a C-terminal fragment (i.e., a native C-terminal fragment), and that the previous claim 25 did not recite sufficient structural features to distinguish the claimed compositions from compositions disclosed by Dolly that include the C-terminal fragment of the native neurotoxin botulinum toxin protein.

Independent claim 25 has been amended to include the subject matter of previous claim 29. Applicant submits that the present claims include sufficient structural features to distinguish the proteins of the present compositions from the proteins and compositions disclosed by Dolly. For example, the present claims recite that the C-terminal portion of the protein is obtained from aerobic bacteria as a single polypeptide chain.

In contrast, Dolly discloses that the C-terminal portion of the botulinum toxin protein is obtained from Clostridial bacteria (i.e., not aerobic bacteria). In other words, the C-terminal portion of the Dolly protein is a native protein fragment (column 5, line 20). As discussed in Example 18 of Dolly, the botulinum toxin protein was obtained as a di-chain that was dissociated into a H (heavy) chain and a L (light) chain (column 29, line 57).

Thus, applicant submits that Dolly does not disclose, teach, or even suggest a soluble recombinant botulinum toxin protein that comprises a C-terminal portion that is obtained as a single polypeptide chain, as recited in the present claims. Therefore, applicant submits that the proteins recited in the

presently claimed compositions, which comprise a C-terminal portion that is obtained as a single polypeptide chain, are structurally different and distinct from the proteins disclosed by Dolly which include native C-terminal portions obtained as di-chains.

Claim 25 is directed to compositions comprising recombinant botulinum toxin proteins comprising a soluble C-terminal portion of a botulinum toxin heavy chain which is produced by a process comprising obtaining the C-terminal portion from aerobic bacteria as a single polypeptide chain. Since Dolly discloses a native botulinum toxin heavy chain, i.e., a heavy chain obtained from the anaerobic bacteria, *Clostridium botulinum*, as a di-chain and has to be dissociated into single chains, Dolly does not anticipate claim 25 and the claims dependent therefrom.

In view of the above, applicant submits that the present claims, that is claims 25-28 and 31, are not anticipated by Dolly or WO 94/21684 under 35 U.S.C. § 102.

#### Double Patenting

Claims 25-30 have been rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as claim 10 of U.S. Patent No. 5,919,665 (the '665 patent).

Applicant submits that a *prima facie* case of same-invention double patenting has not been established since the Office Action lacks the necessary literal infringement analysis. Therefore, applicant requests that the rejection be withdrawn.

Nevertheless, applicant submits that the present claims are not for the "same invention" as claim 10 of the '665 patent. For example, applicant submits that it is possible to literally infringe the present claims without literally infringing claim 10 of the '665 patent.

As just one example, a composition that comprises a soluble fusion protein that comprises at least a portion of Clostridium botulinum C fragment and is not linked to a polyhistidine tag could infringe the present claims and not infringe claim 10 of the '665 patent.

In view of the above, applicant submits that the present claims satisfy the requirements of 35 U.S.C. § 101, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Claims 25-26 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 9, and 12-14 of U.S. Patent No. 6,787,517.

Applicant does not concede to the correctness of the rejection. However, to advance the prosecution of the above-identified application, a terminal disclaimer is being submitted with this response.

In view of the above, applicant submits that the obviousness-type double patenting rejection has been overcome.

Rejections Under 35 U.S.C. § 103

Claim 30 has been rejected under 35 U.S.C. § 103(a) as being obvious over Dolly in view of Williams (U.S. Pat. No. 5,601,823).

As indicated above, claim 30 has been cancelled. Applicant submits the rejection under 35 U.S.C. § 103 is moot.

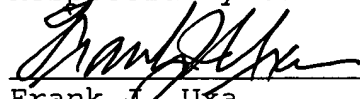
In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present compositions including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

Conclusion

In conclusion, applicant has shown that the present claims are not subject to rejection for double patenting, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 25-28 and 31, are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 10/6/05

Respectfully submitted,

  
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